DETAILED ACTION

In summary, there are 7 claims pending and 7 under consideration. Claims 1-5 are compound claims. Claim 6 is a composition claim. Claim 7 is a nonstatuatory "use" claim. This is the first action on the merits. The application concerns some 5H-pyrrolo[2,3-d]pyrimidine compounds, compositions, synthesis, and uses thereof.

Specification

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

The following title is suggested: Substituted pyrrolo[2,3-d]pyrimidines as Corticotropin Releasing Factor (CRF)Antagonists.

Information Disclosure Statement

The information disclosure statements (IDSs) submitted on 1/4/08, 11/27/07 and 9/1/06 are in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statements are being considered by the examiner.

Claim Objections

This application contains claims 1-7 and 11-19, drawn to an invention nonelected with traverse in the paper of 4/9/2007. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144). See MPEP § 821.01.

Claim 6 is objected to because of the following informalities: the abbreviation/acronym, "CRF" should be spelled-out followed by the abbreviation/acronym in parenthesis. Appropriate correction is required.

Claims 1 and 2 are objected to because of the following informalities: the parenthesis which define formulas [I] and [II] found below formulas [I] and [II] should be removed. Appropriate correction is required.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 7 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example Ex parte Dunki, 153 USPQ 678 (Bd.App. 1967) and Clinical Products, Ltd. v. Brenner, 255 F. Supp. 131,149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 7 is also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either an asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Claims 1-7 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the compound of claim 1 or pharmaceutically acceptable salts of said compound does not reasonably provide enablement for a hydrate of a compound of claim 1. The specification does not provide sufficient guidance nor does it enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

As stated in the MPEP 2164.01 (a), "There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue."

In *In re Wands*, 8 USPQ2d 1400 (1988), factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have need described. They are:

1. the nature of the invention,
2. the state of the prior art,
3. the predictability or lack thereof in the art,
4. the amount of direction or guidance present,
5. the presence or absence of working examples,
6. the breadth of the claims,
7. the quantity of experimentation needed, and
8. the level of the skill in the art.

In the instant case:

The nature of the invention

The nature of the invention is a compound of claim 1, or a pharmaceutically acceptable salt of said compound. There is not a general teaching of solvates or hydrates of compound of claim 1 in the specification.

The state of the prior art and predictability or lack thereof in the art

It is the state of the prior art that the term "hydrate" found in the claims is defined as a compound formed by solvation (the combination of water molecules with molecules or ions of the solute. It has been estimated that approximately one-third of the pharmaceutically active substances are capable of forming crystalline hydrates. Predicting the formation of hydrates of a compound and the number of molecules of water or solvent incorporated into the crystal lattice of a compound is complex and difficult. Each solid compound responds uniquely to the possible formation of hydrates and hence generalizations cannot be made for a series of related compound (See Vippagunta, et al.)

The scope of "hydrate" is not adequately enabled or defined. Applicants provide no guidance as how the compounds are made more active in vivo. Hydrates can not be predicted and therefore are not capable of being claimed if the applicant cannot properly enable a particular hydrate.

The amount of direction or guidance present and the presence or absence of working examples

There is no direction or guidance present in the specification or working examples present in the specification are that defines or relates to what hydrates are being included in the elected invention.

The breadth of the claims

The breadth of the claims is a compound of claim 1 or a pharmaceutically acceptable salt or hydrates thereof.

The quantity of experimentation needed and the level of the skill in the art

While the level of the skill in the pharmaceutical art is high, the quantity of experimentation needed is undue experimentation. One of skill in the art would need to prepare compounds with various solvents without any direction as to what compounds form hydrates with water.

The level of skill in the art is high without showing or guidance as to how to make hydrates of a compound of claim 1 it would require undue experimentation to figure out the temperatures and reaction times that would provide hydrates of the above compounds.

To overcome this rejection, Applicant should submit an amendment deleting the term "hydrates" or provide evidentiary support for hydrates.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The word "derivative" is vague. A derivative is a substance or compound obtained from, or regarded as derived from, another substance or compound. What are these "derivative?" Are the "derivative" covered by the scope of the genus of formula (I)?

Claims 1-7 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The Specification does not provide specific description for "isomers," and just a mere recitation of "isomers" is not sufficient to comply with the written description requirement. Isomers are compounds with different connectivity that have the same molecular formula. There are many different kinds of isomers, e.g. regioisomers, constitutional isomers, stereoisomers, etc. For example, constitutional isomers are isomers with different connectivity that have the same molecular formula. For example, n-propanol and methyl ethyl ether have the same molecular formula, C_3H_8O. What are these "isomers" which are being claimed? What do these look like? Where does Applicant teach how to make these "isomers?" Did Applicant have possession of these "isomers?" Do these isomers still meet the requirements of formula (I) in claim 1? The claim describes the function intended but provides no specific structural guidance to what constitutes a "isomer." Structural formulas, names or both can accurately describe organic compounds, which are the subject matter of claim 1.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claim 1 is rejected under 35 U.S.C. 102(a and e) as being anticipated by O'Yang et. al. (US 20040224964 A1).

The reference teaches compounds of formula (I), wherein X= CR^4R^5, Y= CR^6R^7, R^4, R^5, R^6, R^7= hydrogen, R^1= propyl, R^2= methyl, R^3= hydrogen, Ar= 2,4,6-trimethylphenl and the bond between X and Y is a single bond, see page 8, compound 1. Also note, most of the compounds spanning pages 8-32 anticipate claim 1.

Applicant cannot rely upon the foreign priority papers to overcome this rejection because a translation of said papers has not been made of record in accordance with 37 CFR 1.55. See MPEP § 201.15.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SUSANNA MOORE whose telephone number is (571)272-9046. The examiner can normally be reached on M-F 8:00-5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. James Wilson can be reached on (571) 272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Susanna Moore/
Examiner, Art Unit 1624